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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,214	08/26/2003	Bradley Jascob	5074A-000001/COB	6133
27572	7590	07/25/2008	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303				MEHTA, PARIKHA SOLANKI
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,214	JASCOB ET AL.	
	Examiner	Art Unit	
	PARIKHA S. MEHTA	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 April 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-50,54-58 and 60-85 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 27-50,54-58 and 60-85 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/4/08</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Objections

1. Claims 27, 33, 34-50, 54-58 and 60-85 are objected to because of the following informalities:
Claims 27, 34-37 and 44-50 recite structural limitations for an element which is not positively set forth as part of the invention (the metal object/fluoroscope), and therefore these recitations fail to further limit the claim.
Claims 33 and 50 recite functional language that is unsupported by a positively recited structure that would support such a function.
Claims 38, 39 and 41 recite nothing more than limitations placed upon an element which was not previously set forth as a positive part of the inventive structure (the instrument), and therefore these claims fail to further limit their parent claim.
Claim 44 recites "coils" in line 5 where "coil" should appear.
Claims 68 and 80 recite the term "formed of"; it is unclear whether the invention is inclusive or exclusive of the limitations following this term.
Appropriate correction is required.
2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:
Claim 32 recites "wherein each set of coils includes three sets of coils positioned orthogonal to one another", an embodiment which is not sufficiently supported by the disclosure. It appears that Applicant intended to recite "wherein each set of coils includes three coils positioned orthogonal to one another".
Claim 49 recites "each set of transmitter coils" without proper antecedent basis.
3. Claims 58-84 are objected to as failing to comply with 37 CFR 1.121 (c), which requires all claims to be numbered in ascending numerical order. For the purposes of further examination herein, the second claim 58, canceled in Applicant's previous amendment, is treated as claim 59, and previous claims 59-84 are treated as claims 60-85. Applicant is required to renumber the claims accordingly.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 27-50, 54-58 and 60-85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6,636,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are merely broader than the patented claims, and as such the prior patent reads directly upon the claimed invention. The instant claims broadly recite “an instrument,” whereas the conflicting claims recite “a probe.” In addition to the argument of a probe being an obvious variation of an instrument, Examiner hereby take Official Notice that a variety of medical instruments are well known in the art for use with surgical navigation systems.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 27-50, 54-58 and 60-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle et al (US Patent No. 6,285,902), previously made of record, hereinafter Kienzle ('902), in view of Sandstrom (US Patent No. 3,625,798), hereinafter Sandstrom ('798).

Regarding claims 27-29, 34, 35, 44-46, 54-56, 60-63, 68-72, 75, 76, 81 and 82, Kienzle ('902) teaches a system for use in navigating an instrument through an electromagnetic field including a transmitter array that may be integrally formed or attached to a housing surrounding a C-arm (col. 10 lines 60-63, col. 11 lines 17-27), wherein the transmitters are used to localize the C-arm device during surgery (col. 8 lines 14-53). Kienzle ('902) teaches of magnetically shielding the image intensifier (col. 10 lines 53-59), but does not specify that the housing is operable to substantially shield the imager from the field generated by the coil array, and therefore it is not clear whether the housing of Kienzle ('902) constitutes the shield as claimed in the instant application.

In the same field of endeavor, Sandstrom ('798) teaches a lead shield for an x-ray tube, the shield being operable to prevent interference caused by magnetic fields from affecting the imager (col. 1 line 50-col. 2 line 25). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kienzle ('902) to manufacture the shield of lead in view of the teachings of Sandstrom ('798) in order to achieve the presently claimed invention, as such a modification requires nothing more than the mere combination of prior art elements to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc*, 82 USPQ2d 1385).

Regarding claims 30, 32, 33, 47, 49, 50, 57, 58, 73, 74, and 85, although Kienzle ('902) does not expressly teach that the emitters comprise at least three orthogonal sets having three coils each, the Examiner hereby takes Official Notice that the use of three orthogonal localizing coils during surgical navigation is well known in the art. Furthermore, Kienzle ('902) broadly teaches of using at least three localizing emitters (col. 10 lines 60-62), which, when combined with the known prior art emitters comprising three orthogonal coils each, would result in the claimed invention.

Regarding claims 31 and 48, Kienzle ('902) broadly teaches that, in contrast to being integral to the housing, the emitters may simply be “attached” (col. 11 lines 21-24). It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of invention to modify the system of Kienzle ('902), as previously modified by Sandstrom ('798), so as to attach the coils via an extension member in order to achieve the claimed invention.

Regarding claim 36, Kienzle ('902) teaches that the emitters may be repeatably attached to the C-arm (col. 10 lines 29-33). Repeatable attachment, as taught by Kienzle ('902), implies that the emitters are removably attached as claimed in the instant application.

Regarding claim 37, although Sandstrom ('798) does not require the shield to be integral with the imager, making a combination of prior art elements integral is not considered a patentable modification (see for precedent *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 Fed. Cir. 1983; see also MPEP § 2144 V).

Regarding claims 38, 39, 64, 77, Kienzle ('902) teaches the system to include a surgical tool with an electromagnetic sensor attached at the distal end (col. 7 line 66-col. 8 line 1, col. 9 lines 12-44). Although Kienzle ('902) does not specify that the surgical tool is non-rigid, such surgical tools (catheters, for example) are well known and widely used in the art of image-guided surgery.

Regarding claims 40, 41, 65-67, 78 and 79, Kienzle ('902) teaches the localizing system to use a variety of wireless methods to communicate with the various emitters of the surgical tool and C-arm (col. 9 lines 31-44).

Regarding claims 42 and 43, Kienzle ('902) teaches of using mathematical modeling to account for the effects of interference (col. 10 lines 53-59), and further teaches of storing potentiometer voltages on a memory for future access in a look-up table (col. 10 lines 10-12).

Regarding claim 80, the system of Kienzle ('902) includes a display operable to display navigation information (col. 8 lines 1-11).

Regarding claims 83 and 84, Kienzle ('902) teaches means for calibrating the localization system (col. 9 line 45 – col. 10 line 12).

Response to Arguments

8. Applicant's arguments with respect to claims 27-50, 54-58 and 60-85 have been considered but are moot in view of the new ground(s) of rejection.

9. The declaration filed on 4 April 2008 under 37 CFR 1.131 is sufficient to overcome the Munger (US Patent No. 6,352,363) reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/

Primary Examiner, Art Unit 3737

/Parikha S Mehta/

Examiner, Art Unit 3737